

DEPARTMENT OF HEALTH AND HUMAN SERVICES



Food and Drug Administration Minneapolis District Office Central Region 212 Third Avenue South Minneapolis, MN 55401 Telephone: (612) 334-4100 FAX: (612) 334-4134

April 22, 2004

WARNING LETTER

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Refer to MIN 04 - 24

Kenneth J. Lyrek Co-Owner Lyrek Farms E 9358 1410th Ave Chetek, Wisconsin 54728

Dear Mr. Lyrek:

On February 18-20, 2004, investigators from the Food and Drug Administration (FDA) conducted an inspection at your dairy operation located at 12548 – 930th Street, New Auburn, WI. That inspection confirmed that you offered a dairy cow for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). You also caused the adulteration of an animal drug because the drug was used in a manner that does not conform to its approved use or the extralabel use regulations at Title 21, Code of Federal Regulations, Part 530 (21 CFR 530, copy enclosed). This caused the animal drug to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(5) of the Act.

On or about October 27, 2003, you sold a cow for slaughter as human food through Our inspection documented that you use penicillin to medicate animals at your dairy operation. United States Department of Agriculture (USDA) analysis of tissue samples collected from the animal that you sold identified the presence of 0.34 ppm penicillin in the kidney. A tolerance of 0.05 ppm has been established for residues of penicillin in the uncooked edible tissues of cattle (21 CFR 556.510, copy enclosed). The presence of this drug in edible tissue from this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you hold animals under conditions that are inadequate to prevent animals bearing potentially harmful drug residues from

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entering the food supply. For example, you do not maintain medication records to avoid unsafe residues. You also lack an adequate system for assuring that drugs are not used in a manner contrary to the labeled directions and for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are adulterated within the meaning of Section 402(a)(4) of the Act.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your operations and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not occur. Failure to do so may result in regulatory action (such as seizure or injunction) without further notice to you.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be held responsible for a violation of the Act. The fact that you offered an animal for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your dairy operation into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation that corrections have been made.

Your reply should be directed to Compliance Officer Brian D. Garthwaite, Ph.D. at the address indicated on the letterhead.

Sincerely

W. Charles Becoat

Director

Minneapolis District

xc: William J. Lyrek
Co-owner
Lyrek Farms
E9358 1410th Avenue
Chetek, WI 54728